CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner rejected claims 1-3 under 35 U.S.C. § 112, second paragraph on the grounds that claim is indefinite in the recitation of "substantially equivalent." Although Applicants believe that claims 1-3 are clear and definite, Applicants have amended claim 1 without prejudice to remove the limitation "substantially equivalent" and, therefore, this rejection has been rendered moot.

Further, Applicants respectfully disagree that the definition of "substantially equivalent" as set forth in the specification is not clear. The Examiner's attention is drawn to the further definition of "substantially equivalent" on pages 15 and 17 of the specification, which further defines what is intended by the term "substantially equivalent." For example, on page 15 the specification provides:

Typically, such a substantially equivalent sequence varies from one of those listed herein by no more than about 20% (i.e., the number of individual residue substitutions, additions, and/or deletions in a substantially equivalent sequence, as compared to the corresponding reference sequence, divided by the total number of residues in the substantially equivalent sequence is about 0.20 or less). Such a sequence is said to have 80% sequence identity to the listed sequence. In one embodiment, a substantially equivalent, e.g., mutant, sequence of the invention varies from a listed sequence by no more than 20% (80% sequence identity); in a variation of this embodiment, by no more than 10% (90% sequence identity); and in a further variation of this embodiment, by no more than 5% (95% sequence identity). Substantially equivalent, e.g., mutant, amino acid sequences according to the invention generally have at least 80% sequence identity with a listed amino acid sequence.

Additionally, on page 17, in the section entitled "POLYNUCLEOTIDES AND NUCLEIC ACIDS OF THE INVENTION," the specification provides:

The polynucleotides of the invention also include nucleotide sequences that are substantially equivalent to the polynucleotides recited above. Polynucleotides according to the invention can have at least about 80%, more typically at least about 90%, and even more typically at least about 95%, sequence identity to a polynucleotide recited above. The invention also provides the complement of the polynucleotides including a nucleotide sequence that has at least about 80%, more typically at least about 90%, and even more typically at least about 95%, sequence identity to a polynucleotide encoding a polypeptide recited above. The polynucleotide can be DNA (genomic, cDNA, amplified, or synthetic) or RNA such as mRNA or an antisense RNA. Methods and algorithms for obtaining such polynucleotides are well known to those of skill in the art and can include, for example, methods for determining hybridization conditions which can routinely isolate polynucleotides of the desired sequence identities.

Thus, the specification specifies the metes and bounds of the term "substantially equivalent." The specification provides that polynucleotides that are substantially equivalent to

SEQ ID NO:1 "have at least about 80%, more typically at least about 90%, and even more typically at least about 95%, sequence identity" to the polynucleotide of SEQ ID NO:1.

Based on the foregoing, Applicants respectfully request that the claim rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Written Description

The Examiner rejected claims 1-3 under 35 U.S.C. § 112, first paragraph on the grounds that the specification does not contain a written description of the invention. The rejection is improper.

In general, a written description rejection under § 112, first paragraph should not be made against originally filed claims. As the MPEP notes, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. MPEP, 8th Edition, August 2001 at 2100-158 to 159 citing In re Wertheim, 541 F.2d 257, 263 (CCPA 1976). Consequently, rejection of an original claim for lack of written description should be rare. Id.

In any case, the Examiner's assertion that the specification does not contain a written description of the claimed invention is flatly inconsistent with the plain text of the specification and with the law. The Examiner asserts that the written description is inadequate because the claims encompass "a large variable genus" but the specification only discloses a single species.

As such there is no requirement that more than one species be disclosed to support a genus. In re Rasmussen, 650 F.2d 1212, 1214 (CCPA 1981). Therefore, the Examiner's assertion is not supported by the law.

More importantly, though, the Examiner's assertion is not supported by the specification. The specification does disclose species other than SEQ ID NO:1 to support the claimed genus. See, for example, Example 8 which discloses a mutant of SEQ ID NO:1. The disclosed mutation in SEQ ID NO:1, the coding sequence for CARM1, results in the "replacement of three amino acids, valine 189, leucine 190, and aspartic acid 191, with

alanines." Specification pp. 40-41, p. 8 (discussion of Figure 6) and Figures 6A and 6B. See also discussion of Figure 2 on page 7 and Figure 2, which discloses a fragment of SEQ ID NO:1 – a 0.6 kb BamHI cDNA fragment, representing CARM1 codons 3-198.

Thus, the Examiner's assertion that claims 1-3 do not meet the written description requirement because only a single species of the claimed genus is disclosed is clearly untenable.

Enablement

The Examiner further rejected claims 1-3 under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner asserts that the specification, "while being enabling for SEQ ID NO:1, does not reasonably provide enablement for any nucleic acid comprising a sequence substantially equivalent to SEQ ID NO:1 or a fragment thereof of at least 40 nucleotides."

As an initial matter, Applicants have amended claim 1 to replace the "substantially equivalent" limitation with a sequence identity limitation, thereby, to a certain extent, rendering the rejection moot. Additionally, as shown by the"Written Description" discussion *supra*, nucleic acids other than SEQ ID NO:1 are enabled by the specification.

Futher, the Examiner's attention is drawn to Example N of the document entitled "Training Materials for Examining Patent Application with Respect to 35 U.S.C. section 112,. First Paragraph –Enablement Chemical/Biotechnical Applications," which is available at http://www.uspto.gov/web/offices/pac/dapp/oppd/1pecba.htm. Example N clearly establishes that the rejection of claims 1-3 for lack of enablement is improper. The analysis section of Example N states, with reference to a claim similar to instant claim 1, that because "the state of the art is such that it would have been routine to make the DNA given the sequence, it certainly would not require undue experimentation to make the DNAs claimed in claim 1." Furthermore, the fact that the genus is very large is not an impediment because "each embodiment can be readily identified using the genetic code, synthesized using conventional methods, and used in the manner taught in the specification without undue experimentation."

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(a)

The Examiner rejected claims 1-3 under 35 U.S.C. 102(a) as being anticipated by Chen et al. Applicants respectfully submit that this rejection is improper because Chen et al. was published after the effective filing date of the present application. Chen et al. was published on June 25, 1999. The instant application claims priority to provisional application 60/112,523 filed December 15, 1998, giving it an effective filing date that predates Chen et al.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)

The Examiner rejected claims 1-3 under 35 U.S.C. 102(e) as being anticipated by Lal et al. Applicants have amended claim 1 to overcome this reference. Claim 1 now requires an 80% sequence identity to nucleotides 1-2100 of SEQ ID NO:1, which is not possessed by SEQ ID NO:6 of Lal et al. By the Examiner's own admission, Lal et al. teach a sequence that is only 83% identical to about 73% of SEQ ID NO:1 (2567-290=2277 nucleotides, which is about 73% of SEQ ID NO:1's 3125 nucleotides). Therefore, the cited sequence from Lal et al. has a less than 60% sequence identity SEQ ID NO:1.

Lal et al., of course, do not anticipate new claims 42, 45 and claims dependent thereon because these claims require a sequence identity of 90% or more, which, as the Examiner admits, is not possessed by the sequence taught by Lal et al.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

The Examiner rejected claims 1-3 under 35 U.S.C. 102(b) as being anticipated by GenBank entries AA396116 and AA215095. Applicants submit that amended claim 1 and new claims 39-47 are not anticipated by these references. Claim 1 has been amended so that the nucleotide claimed in claim 1 has a sequence identity to nucleotides 1–2100 of SEQ ID NO:1. The cited GenBank entries do not disclose nucleotides that have such sequence identity. Clearly, then, GenBank entries AA396116 and AA215095 do not anticipate amended claim 1 or claims dependent thereon. Similarly, new claims 42, 45 and claims dependent thereon also require sequence identity to nucleotides 1–2100 of SEQ ID NO:1 and, therefore, are also not anticipated by GenBank entries AA396116 and AA215095.

Applicants, therefore, respectfully request the Examiner to withdraw the rejections under 35 U.S.C. § 102.

CONCLUSION

Accordingly, in view of the above amendments and remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (213) 680-6678.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1192.

Dated: January 7, 2002

Respectfully submitted,

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